UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

APOTHECUS PHARMACEUTICAL CORP., Plaintiff, - against - PHARMASOL CORPORATION, Defendant.	21 cv. 867 COMPLAINT Plaintiff requests a trial by jury.

Plaintiff Apothecus Pharmaceutical Corp., by its attorney, Stanley K. Shapiro, Esq., complaining of defendant, alleges as follows:

The Parties

1. Plaintiff Apothecus Pharmaceutical Corp. ("Apothecus") is a New York corporation, with principal executive office at 220 Townsend Square, Oyster Bay, County of Nassau, State of New York, engaged in the business of developing, manufacturing, marketing and commercially distributing certain over-the-counter health care products under its brand name "VCF".

2. On information and belief, defendant Pharmasol Corporation ("Pharmasol"), is a Delaware corporation, with principal executive office in the Commonwealth of Massachusetts, at One Norfolk Avenue, South Easton, Massachusetts. On information and belief, Phamasol regularly does and solicits business, and derives substantial revenue from goods used or consumed in New York.

3. At all relevant times, defendant Pharmasol held itself out as and was a contract manufacturer for pharmaceutical products subject to FDA regulation. In particular,

Pharmasol was engaged by plaintiff as a contract manufacturer of one of plaintiff's products, contracting to supply goods and services for Apothecus in New York.

Jurisdiction and Venue

4. Federal jurisdiction is predicated on diversity of citizenship, 28 U.S.C. § 1332. This action is of a civil nature involving, exclusive of interest and costs, a sum in excess of $75,000. The matter in controversy herein is wholly between citizens of different States.

5. Venue is appropriate in this district pursuant to 28 U.S.C. §1391(a)(2) or (3), in that defendant resides out of New York, and is subject to long arm jurisdiction in New York for this action pursuant to NY CPLR 302.

As and for a First Cause of Action
(Breach of Contract)

6. For more than twenty-five years and continuously through and until November 2019, plaintiff held proprietary rights and trade marks to and developed, manufactured and commercially distributed under its proprietary VCF brand name several vaginal contraceptive health care products, sold over-the-counter in pharmacies throughout the United States and Canada, including since about 1996, a VCF brand vaginal contraceptive foam in an aerosol spray container (the "Product") under plaintiff's brand name.

7. Pharmasol held itself out as a contract manufacturer, qualified with expertise to manufacture aerosol pharmaceutical products subject to FDA regulation. Pharmasol's website represents itself as having "significant expertise and a thorough understanding of aerosols"; and proclaims that its "state of the art cGMP facilities" are "designed and constructed to provide optimum efficiency, safety and regulatory compliance" for the manufacture and packaging of aerosols, liquids and semi-solids.

8. Sometime prior to 2017, plaintiff arranged with Pharmasol to serve as a contract manufacturer of Apothecus' product vaginal contraceptive foam packaged in a 0.6 oz. aerosol spray container under Plaintiff's VCF label and trade name (the "Product").

9. In January 2017, plaintiff and defendant entered a written contract , denominated Quality Agreement Commercial Product (the "Quality Agreement"), for the manufacture and testing of the Product, including quality inspection and quality assurance, between defendant Pharmasol as "Supplier" and plaintiff Apothecus as "Client". (A copy of the Quality Agreement is annexed hereto as Exhibit 1, and incorporated herein.)

10. The Quality Agreement set forth quality management obligations upon Phamasol, for its manufacture of the Product as contract manufacturer for Apothecus. which Pharmasol breached, causing Apothecus to incur substantial damages.

11. Under the terms of the Quality Agreement Pharmasol was obliged to conduct operations in compliance with current Good Manufacturing Practices ("cGMP") regulations and other applicable FDA regulations (Quality Agreement Section 4.1.1).

12. The Quality Agreement specified that "PHARMASOL will ensure that Product(s) are manufactured and tested in strict compliance with current US Federal Good Manufacturing Practices (GMP) (US 21 CFR parts 210 and 211 for the manufacture of finished medicinal product) as applicable" (Quality Agreement Section 4.2.3).

13. On information and belief, the Pharmasol's manufacturing facility ("Pharmasol Plant") where it manufactured and tested the Product under the contract with plaintiff, was inspected by the FDA in July and August 2018.

14. Under the terms of the Quality Agreement, Pharmasol was obliged to notify Apothecus within three business days of receipt of any notice of inspection by the FDA;

and Pharmasol was obligated to notify Apothecus within one day of any regulatory authority request of product samples, batch documentation, or other information related to the Product. Under the Quality Agreement, Pharmasol was obligated to notify on daily basis of any regulatory findings or violations, and must obtain duplicate copies of records for Apothecus.

15. Pharmasol failed to notify Apothecus of the July and August 2018 inspections of the Pharmasol Plant, and failed to notify Apothecus of requests made by the FDA with respect to the Product. Pharmasol also failed to notify Apothecus of the regulatory findings issued by the FDA with respect to the inspections.

16. Under the Quality Agreement, Pharmasol was obliged to provide Apothecus, for review and comment, a copy of any Pharmasol response to any regulatory authority involving the Product, no less than five business days prior to submission of the response to the regularity authority.

17. Pharmasol failed to provide Apothecus with copies of any of its responses to the FDA.

18. In or about March 2019, the FDA, Division of Pharmaceutical Quality Operations, issued a Warning Letter to Pharmasol finding that Pharmasol failed to comply with cGMP with respect to the manufacture and testing of the Product. The Warning Letter to Pharmasol in March 2019 summarized the FDA's findings of violations.

19. The FDA inspection of Pharmasol uncovered significant violations by Pharmasol of current Good Manufacturing Practice regulations for finished pharmaceuticals effecting the Product.

20. The FDA reported in its Warning Letter to Pharmasol, that because Pharmasol's methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to cGMP, Pharmasol's drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

21. The FDA Warning Letter detailed specific violations observed by the FDA investigators relating to Pharmasol performance of manufacturing and testing of the Product delivered under contract for Apothecus.

22. The Quality Agreement required Pharmasol to notify Apothecus within one business day of receipt of any warning letters from any regulatory agency that relates to the Product (Section 4.2.4).

23. Yet, Pharmasol failed to notify Apothecus of the FDA Warning Letter after Pharmasol's receipt of that letter in March 2019.

24. Pharmasol concealed the FDA regulatory inspections and letters from Apothecus.

25. The FDA found that Pharmasol violated federal regulations (21 CFR 211.192) by failing to thoroughly investigate unexplained discrepancy or failure of the batch or any of its components to meet specifications, in respect to two batches of the Product, Lots 31560 and 31561.

26. In July 2017, Pharmasol found that the Product, Vaginal Conception Foam 0.6 oz., Lots 31560 and 31561 were found Out-of-Specification ("OOS") as samples were found leaking (Lab OOS #17-042, 7/12/17). (Out-of-Specification results for elevated leak rate for the two lots of the Product are documented (reference Laboratory OOS# 17-042).)

27. According to the FDA Warning Letter in 2019, deficiencies in Pharmasol's stability program found by the FDA in the 2018 inspection of Pharmasol were repeat findings from FDA inspections in 2013, 2014 and 2015 that had resulted in Phamasol being cited. (Pharmasol had concealed from plaintiff the prior 2013, 2014 and 2015 FDA inspection findings.)

28. In July 2017, Pharmasol had represented to Apothecus that Lots 31560 and 31561 of the Product were on 14-day hold for initiation of weight loss testing. But Phamasol wrongfully cancelled the testing without notifying Apothecus, without written justification and without identifying reason for the Out-Of-Specification results, and released the two Lots to Apothecus for commercial distribution.

29. Pharmasol concealed from Apothecus, Pharmasol's cancelation of its Quality Assurance ("QA") and Quality Improvement ("QI") testing, and the Product manufacturing and quality control Out-Of-Specification ("OOS") failures.

30. Before each lot was delivered to Apothecus for release Pharmasol was obliged under the Quality Agreement to provide Apothecus with a "Certificate of Analysis," to be signed by the Pharmasol Quality Assurance, for each delivered lot of Product. The required "Certificate of Analysis" meant a certificate from Pharmasol certifying that: (a) the Product was manufactured, packaged, tested, labeled, stored and shipped in accordance with cGMPs and the Specifications and relevant standard operating procedures of Pharmasol; (b) the Product meets all in-process specifications, no Investigations remain unresolved, and all reconciliations and accountability have been satisfactorily completed; and c) the product identification, lot number, and final product yield. (See Quality Agreement Section 4.8.3).)

31. The Quality Agreement also called for Pharmasol to deliver to Pharmasol a Certificate of Compliance for the Product lot being released, which shall specify the Product description, the Client item number, the quantity released and the Product expiration date, if applicable. Pharmasol was obliged to certify to Apothecus prior to delivery of a lot of the Product for commercial release that the batch has been manufactured in accordance with cGMPs and the Specifications; the lot was packaged in accordance with cGMPs, the Specifications, and all pertinent Pharmasol SOP's. (See Quality Agreement Section 4.8.3).)

32. In August 2017, Pharmasol provided Apothecus with signed Certificates of Compliance and signed Certificates of Analysis for Lots 31560 and 31561, respectively, falsely certifying that Pharmasol had manufactured, packaged, tested, labeled, stored and shipped each subject lot of Product in accordance with Federal cGMP regulations (CFR Title 21, Parts 210 and 211), the contract Specifications and relevant standard operating procedures of Pharmasol; and that the Product meets all in-process specifications, no Investigations remain unresolved, and all reconciliations and accountability have been satisfactorily completed. (Copies of the Certificates of Compliance and Certificates of Analysis are attached hereto as Exhibits 2 and 3.)

33. These Certificates of Compliance and Certificates of Analysis for Lots 31560 and 31561 signed and delivered by Pharmasol in August 2017 were materially false and inaccurate.

34. Apothecus took delivery and commercially distributed the two lots of the Product in reliance upon the false and inaccurate Certificates of Compliance and Certificates of Analysis for Lots 31560 and 31561.

35. On or about April 15, 2019, the FDA began an unannounced inspection of Apothecus, triggered by the violations issued against Pharmasol, that Pharmasol was concealing from Apothecus.

36. Only after this did Apothecus became aware that the FDA made regulatory inspections of Pharmasol resulting in a Warning Letter to Pharmasol regarding the Product. Thereafter, following the FDA inspection of Apothecus on April 15, 2019, Pharmasol repeatedly represented to Apothecus it would review, assess and report to Apothecus, representing for example that Phamasol "is working on making sense of all data and is working on writing it up for [Apothecus'] review", and that Pharmasol's report to Apothecus was forthcoming. This representation was made repeatedly through the date of the Product recall in November 2019, without compliance by Pharmasol (continuing to the present).

37. Apothecus notified Pharmasol of the urgency of the information and report, including leading up to and on November 5, 2019, informing Pharmasol that it was meeting with FDA to discus recall of the two Lots, and that Pharmasol was waiting in urgent need of the delayed data, information and report from Pharmasol owed and promised by Pharmasol. Apothecus advised that there was urgent need of a conclusion and/or additional information to conclude with the FDA.

38. Pharmasol remained in default of supplying to Apothecus required information and report.

39. The finished Product delivered by Pharmasol failed to meet final Product Specifications as established and agreed upon between it and Apothecus. Deviations from Product Specifications were wrongfully concealed by Pharmasol.

40. In November 2019, Apothecus was compelled to recall the two Lots of the Product that were deemed by the FDA to be Out-of-Specification and deficiently manufactured and tested by Pharmasol in violation of applicable cGMP.

41. On or about November 8, 2019, the FDA issued a Warning Letter to Apothecus. The Warning Letter and the violations raised therein were proximately caused by and derived from Pharmasol's default of obligations it owed to Apothecus under the Quality Agreement.

42. The FDA held Apothecus accountable for its contract manufacturer Pharmasol's violations of current Good Manufacturing Practice (cGMP) with respect to the Product, that the FDA had found on the inspections of Pharmasol, that Phamasol had concealed from Apothecus.

43. The FDA Warning Letter to Apothecus referred to violations attributable to Pharmasol of cGMP regulations for combination products with respect to the Product.

44. Pharmasol breached the Quality Agreement to operate and perform the manufacturing services within the specifications, failed to notify Apothecus of the FDA inspections, and to give advance copies to Apothecus of Pharmasol's responses to the FDA, failed to provide Apothecus with notice and a copy of the FDA's Warning letter to Pharmasol, fraudulently concealing from Apothecus QA and QI departures and the regulatory inspections.

45. Phamasol did not comply cGMP and regulatory requirements with respect to the Product released as Lots 31560, 31561. Among other respects, Pharmasol did not comply

with cGMP regulatory requirements with regard to: quality control (CFR 211.22), deviation from written procedures (CFR 211.100), testing and release for distribution (CFR 211.165), and laboratory records (CFR 211.194).

46. Pharmasol failed to adhere to the Test Procedure for Leakage Test for the VCF finished Product and stability samples.

47. Pharmasol concealed from Apothecus the FDA inspection and regulatory communications between Pharmasol and the FDA and failed to report to Apothecus the FDA's Form 483 and associated Warning Letter with regards to Phamasol's Quality Units infractions in regard to the Product.

48. Necessary controls and techniques with regard to product quality were not in place or followed by Pharmasol's quality unit personnel.

49. Phamasol breached the Specified Test Procedures for Leakage Testing for the Vaginal Contraceptive Foam Finished Product and Stability Samples, as well as Investigations and release review. (STP-025 Test Procedure).

50. Pharmasol's Quality Unit personnel were not adequately trained in cGMP and/or company procedures.

51. Pharmasol's internal company procedures with regards to Investigations, Deviations were never concluded or finalized.

52. Pharmasol wrongfully, wilfully and fraudulently concealed its breach of the Quality Agreement from Apothecus.

53. As soon as Apothecus first learned about Pharmasol's breach and default of the Quality Agreement, once Apothecus was contacted by the FDA beginning on April 15, 2019, Apothecus notified Pharmasol. Apothecus continued to put Pharmasol

on notice of the FDA investigation and demands arising from Pharmasol's violations leading up the recall of the Product in November 2019 due to Pharmasol's breach of the Quality Agreement.

54. Apothecus notified Pharmasol of the decision to recall the Product in November 2019, within a reasonable time after Apothecus learned that the recall was necessary due to Pharmasol's breach of the Quality Agreement, upon meeting with the FDA in early November 2019.

55. By reason of the foregoing, defendant has materially breached its contract with plaintiff, and plaintiff has been damaged thereby.

56. By reason of the foregoing, plaintiff has and will incur substantial extra costs and expenses relating to the regulatory proceedings and the Product recall, has suffered significant loss of past and future sales and revenues, and profits, incurred damaged and destroyed inventory, has suffered substantial harm and damage to its trade name, reputation and good will, is entitled to refund of payments made to defendant, due to the Warning Letter was caused to be encumbered from obtaining Certification of Pharmaceutical Product from the FDA, instrumental for achieving regulatory approval in foreign countries for its products, has caused a halt to progress on registrations in Hong Kong and the European Union, and has been otherwise damaged.

57. As a result and consequence of the foregoing, the Product has lost its commercial distribution sales and market positions in leading retailers such as Walmart, the Product was discontinued and plaintiff has lost sales and revenue of the

Product going forward of approximately Five Hundred Thousand ($500,000) Dollars per year.

58. By reason of defendant's aforesaid breach of the Quality Agreement, plaintiff has sustained direct, incidental and consequential damages, altogether in the sum of Ten Million ($10,000,000) Dollars, plus interest.

As and for a Second Cause of Action
(Fraud in the Inducement, Fraud and Deceit)

59. The allegations contained in paragraphs 1 through 58 are realleged as if repeated in full.

60. On information and belief, Pharmasol wilfully, wrongfully and fraudulently omitted to disclose, misrepresented and concealed from Apothecus FDA communications and findings in regard to inspections in 2013, 2014 and 2015, and deficiencies found then by the FDA in Pharmasol's stability program.

61. On information and belief, Pharmasol knowingly omitted to disclose to Apothecus, wrongfully and fraudulently withheld, concealed and covered-up from Apothecus the prior (2013, 2014 and 2015) FDA findings and citations, to induce Apothecus to enter the Quality Agreement in January 2017 and continue Phamasol as a contract manufacturer in reliance on Pharmasol's misrepresentations and omissions.

62. Pharmasol made material misrepresentations and omissions of material facts, which it knew to be false, with the intent that plaintiff rely thereon when the Quality Agreement was entered into with plaintiff in January 2017.

63. In August 2017, Pharmasol willfully, wrongfully and fraudulently provided to Apothecus Certificates of Compliance and Certificates of Analysis for Lots 31560 and

31561, that Phamasol knew or should have known contained false, inaccurate and misleading representations and omissions of material fact, Pharmasol did so with the purpose and intent of inducing Apothecus to accept delivery and release for commercial distribution the said Lots of the Product under Apothecus' trade name, in reliance upon the material misrepresentations contained in the Certificates of Compliance and Certificates of Analysis certified by Pharmasol.

64. In and after July 2017, Pharmasol made false, inaccurate and misleading representations and omissions of material fact to Apothecus that Pharmasol was conducting testing to assure compliance, when Pharmasol knew or should have known that it had cancelled the tests without Apothecus' knowledge or consent.

65. In and after July 2017, Pharmasol represented to Apothecus that Pharmasol was conducting testing to assure compliance, but secretly cancelled the tests, while knowing that Apothecus was commercially distributing the Product in reliance on Pharmasol's representations. Phamasol omitted to disclose and knowingly and wilfully concealed such facts from Apothecus with the knowledge and intent that Apothecus accepted delivery and continue commercial distribution of the Lots of the Product in reliance on Pharmasol's representations.

66. Pharmasol wilfully, wrongfully and fraudulently omitted to disclose and concealed from Apothecus the FDA regulatory inspections, actions and communications, including the March 2019 FDA Warning Letter to Phamasol, and its violations of cGMP, regulations and contract specifications, with the intent to deceive and defraud Apothecus.

67. Pharmasol wrongfully and fraudulently concealed the FDA regulatory inspections and letters; and Pharmasol's cancellation of its QA and QI testing, and the Product manufacturing and quality control OOS failures.

68. At all times relevant hereto, Pharmasol knew that the aforesaid representations, acts and omissions were materially false, deceptive, inaccurate and/or misleading, and that plaintiff would rely thereon; and Pharmasol acted with the intent to deceive, defraud and conceal the true state of facts from Apothecus.

69. Apothecus reasonably relied to its ultimate damage and detriment on the representations, acts and omissions of Pharmasol.

70. Further, in the circumstances alleged herein, defendant engaged in egregious or fraudulent conduct evincing such wanton and/or malicious dishonesty as to imply a criminal indifference to civil obligations, sufficient to warrant the imposition of punitive damages under New York law. Plaintiff has been damaged and is entitled to direct, incidental and consequential and punitive damages by reason of defendant's unlawful and fraudulent acts and omissions.

71. As a proximate result of the false, deceptive, inaccurate and/or misleading and fraudulent acts, omissions, misrepresentations and conduct of Phamasol, plaintiff has been caused to suffer direct, incidental and consequential damages, altogether in the sum of Ten Million ($10,000,000) Dollars; and are entitled also to exemplary or punitive damages in the further amount of $10,000,000.

WHEREFORE, plaintiff demands judgment against defendants, jointly and severally, in the sum of **TEN MILLION DOLLARS ($10,000,000)**, or such other amount as the jury shall deem to be reasonable, equitable, just and proper, together with

punitive and exemplary damages on the second cause of action in the added amount of **TEN MILLION DOLLARS ($10,000,000)**, or in such added amount as the jury or trier of fact shall deem to be reasonable, equitable, just and proper, and to the full extent allowed by law; together with interest thereon, at the New York statutory rate, from the date of January 19, 2017, and costs and disbursements, and reasonable attorneys' fees of this action to the full extent allowed by law; and grant such other relief as is just and proper.

Plaintiff requests a trial by jury.

Dated: New York, New York
February 17, 2021

/s/ *Stanley K. Shapiro*

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